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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for a new animal drug application (NADA) from Merial Ltd., to Vétoquinol N.-A., Inc.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iseline, NJ 08830-3077, has informed FDA that it has transferred the ownership of, and all rights and interests in, the approved NADA 113-510 (phenylbutazone granules) to Vétoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J0K 1H0. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) and 520.1720b(b) to reflect the change of sponsor.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for "Vétoquinol N.-A., Inc.," and in the table in paragraph (c)(2) by numerically adding an entry for "059320" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
Vétoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, JOK 1H0	059320

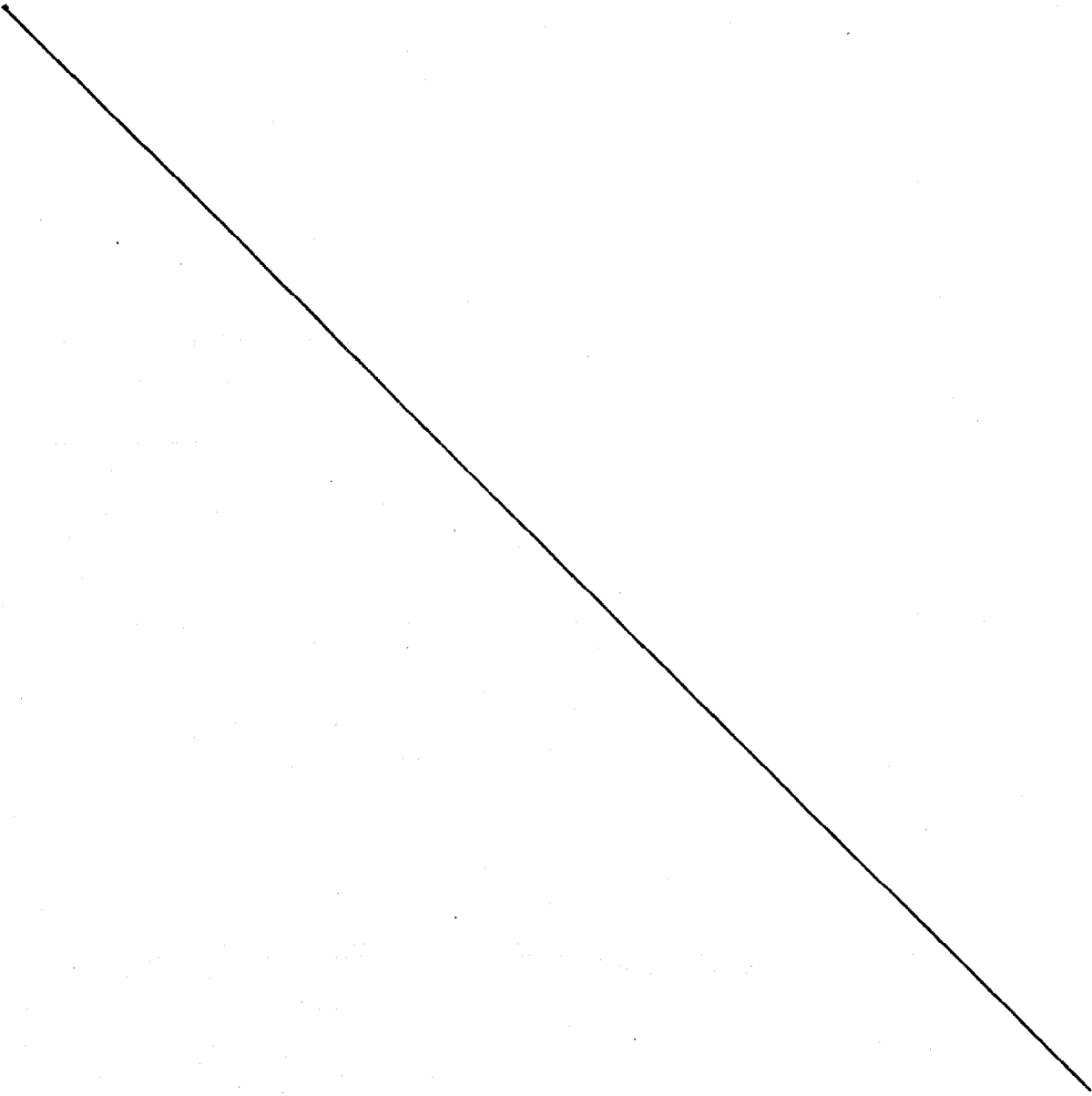
(2) * * *

Drug labeler code	Firm name and address
* 059320 *	* Vétoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J0K 1H0 *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

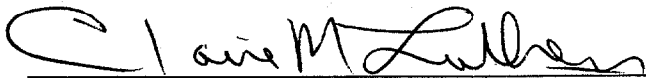
Authority: 21 U.S.C. 360b.



§ 520.1720b [Amended]

4. Section 520.1720b *Phenylbutazone granules* is amended in paragraph (b) by removing “050604” and by adding in its place “059320”.

Dated: 3/17/2000
March 17, 2000



Claire M. Lathers
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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